

REMARKS

The Office Action mailed December 26, 2007 has been carefully reviewed and considered by applicant.

By the present Amendment, the claims in the present application have been amended to more particularly point out and distinctly claim the subject matter believed allowable over the references applied by the Examiner. In the Office Action, claims 1-3, 11-14, 20, 24, 25, 27, 28, 60, 61, and 66-76 have been rejected under 35 USC §102(b) as being anticipated by Rottem U.S. Patent No. 6,032,678 (hereinafter Rottem). Claims 1-3, 5-11, 13, 14, 16, 17, 20, 22, 24, 25, 27, 28, 61, 66, 67, and 69-76 have been rejected under 37 USC §102(e) as being anticipated by Iliff U.S. Published Patent Application No. 2005/0010088 (hereinafter Iliff). Claims 12, 13, 66, 70, and 71 have all also been rejected under 35 USC §112 as being indefinite.

By the present Amendment, applicant hereby cancels claims 20, 22, 24, 25, 27, 60, 61, 66, 67, and 70 and adds new claims 77-84. Therefore, claims 1-3, 5-14, 16, 17, 28, 68, 69, and 71-84 are pending in the present application and are believed allowable for the reasons stated herein.

Claim Objections

Claim 11 has been amended to correct the typographical errors pointed out by the Examiner. Applicant requests that this objection be withdrawn with respect to claim 11.

Claim Rejections Under 35 USC §112

Claims 12, 13, 66, 70, and 71 have all been rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. By the present Amendment, claims 12 and 13 have been amended such that proper antecedent basis now exists for the step of determining at least one algorithm. Therefore, claims 12 and 13 are believed to be definite and distinctly claim the subject regarded as the invention. Also, by the present Amendment, claims 66 and 70 have been cancelled, thus rendering the rejection of these claims moot.

Claim 71 has been rejected under §112 as being dependent from a rejected claim 70. As claim 70 has been canceled, claim 71 has been amended and is now dependent from claim 69, which is believed definite. Therefore, it is believed that claims 12, 13, and 71 are all definite and particularly point out and distinctly claim the subject matter regarded as the invention.

Claim Rejections Under 35 USC §102(b)

Claims 1-3, 11-14, 28, 68, 69, and 71-76 all presently stand rejected as being anticipated by Rottem.

Rottem teaches a device and system for use in tandem with diagnostic imaging tools to enhance the reliability of diagnosis by providing additional guidance to a reviewing clinician. In the system of Rottem a diagnostic image is obtained and the system, either automatically or semi-automatically, identifies the organ systems that may be depicted in the image. (column 6, lines 38-49) This determination merely identifies the possible organs encountered during a procedure. The identified organs are listed along one axis of a matrix with the other axis defining possible conditions that may affect those organs. (column 5, lines 4-10). This matrix provides an index to the clinician wherein the clinician may select any intersection between an organ and a condition in order to obtain additional information regarding the selected organ and the selected condition. (column 5, lines 47-49) The information displayed to the clinician may include a picture of the organ affected with the condition and may also include other information presented in textual, graphic, or video format that provides additional information for the clinician to determine a diagnosis. (column 5, lines 52-61)

While Rottem describes this a "differential diagnosis" the additional information provided by Rottem comes in two forms, that of identifying conditions similar the one selected by the clinician (column 6, lines 5-7) and listing the criteria required for diagnosis of the selected condition (column 6, lines 16-20). The "differential diagnosis" taught by Rottem is merely a presentation of library information regarding a condition selected by the clinician. Therefore, Rottem merely teaches an indexing system whereby the clinician may quickly and

accurately obtain background and diagnostic information regarding a selected organ system and selected condition.

Claim 1

The Examiner has rejected claim 1 as being fully anticipated by Rottem. Applicant submits that Rottem fails to teach the first logic rule set and the second rule set that generate a first diagnostic interpretation and a second diagnostic interpretation. While Rottem does not disclose any specifics detailing how the functions can be performed, the Examiner has pointed to the generation of the matrix as the first logic rule set generating a first diagnostic interpretation and the "differential diagnosis" as the second logic rule set generating the second diagnostic interpretation. Applicant submits that Rottem fails to disclose the use of a first and a second logic rule set to obtain the functions cited by the Examiner, thus failing to anticipate claim 1. Additionally, the applicant submits that the functions cited by the Examiner fail to teach a first and second diagnostic interpretation, but rather are merely the presentation of library information by a indexing interface.

Rottem fails to teach the claimed controller generated first and second diagnostic interpretations utilizing the first and second logic rule set, in that the information presented by Rottem is dependent upon the selection of, or other input of information by the clinician, rather than an analysis of the real-time physiologic data stream. As taught by the system of Rottem, the same information would be presented to the clinician upon the same clinician selection of an organ system and a condition regardless of the diagnostic image or images currently loaded into the system. Thus, Rottem fails to anticipate claim 1.

Claims 2, 3, and 68

Claims 2, 3, and 68 all depend directly and/or indirectly from independent claim 1, which is herein believed allowable. Therefore, dependant claims 2, 3, and 68 are also believed allowable for the reasons stated above as well as the subject matter recited therein.

Claim 11

Presently amended claim 11 has been rejected as being fully anticipated by Rottem. As amended, claim 11 requires the steps of applying at least one rule-based algorithm from a

first set of the rule-based algorithms to the acquired physiological data stream; generating a first diagnostic interpretation based on an application of the at least one rule-based algorithm from the first set to the acquired physiological data stream; applying at least one rule-based algorithm from a second set of rule-based algorithms to the acquired physiological data stream; generating a second diagnostic interpretation based on the application of the at least one rule-based algorithm from the second set to the acquired physiological data stream.

Rottem fails to teach the requirements of claim 11 identified above. First, Rottem fails to teach a plurality of rule-based algorithms including a first set and a second set. Rather, Rottem teaches an indexing system for obtaining specific pieces of information from a plurality of information. The clinician makes selections to indicate the information that the clinician desires to view, rather than the system selecting the information displayed based on the application of set of rule-based algorithms to the physiological data.

As stated in claim 11, the sets of algorithms must be applied to the acquired physiological data stream, to generate a first and a second diagnostic interpretation. With respect to generating the first diagnostic interpretation, the generation of the "core matrix" as disclosed by Rottem is not a first diagnostic interpretation because the "core matrix" simply identifies organs that may or may not be encountered during an identified diagnostic imaging procedure and the conditions that could affect those organs. There is no discretion in the data that is displayed in the "core matrix" based on the diagnostic image that could be considered to be a diagnostic interpretation.

As disclosed by the figures, and with exemplary reference to Figure 1, (note that Rottem fails to disclose any other embodiment of the "core matrix" with respect to the relevant features) the conditions that may affect the identified organ systems include everything from cancer and inflammatory diseases to pregnancy, infertility, and menopause. The list of conditions even include a "other" option which presumably would contain other conditions that do not specifically fall within any identified category. Thus, there is no diagnostic interpretation being conducted in the generation of the "core matrix". The "core matrix" merely lists all the possible conditions that may affect the identified organ systems. This list of conditions is not dependent upon any specific analysis of the diagnostic image itself and does not result from the analysis of rule-based algorithms applied to the acquired

diagnostic image. Thus, Rottem fails to teach the application of a first rule set to the acquired physiological data to generate a first diagnostic interpretation.

Similarly, Rottem also fails to teach the application of a second rule set to the acquired physiological data to produce a second diagnostic interpretation. Rottem teaches that after the display of the core matrix to the clinician, the clinician may select any one of the intersections between an organ system and a condition. This is a clinician action and is irrespective of the acquired diagnostic image. This clinician action causes Rottem's system to display textual, graphical, and video reference information to the clinician regarding the selected organ system and selected condition. Thus, the system of Rottem does not apply a second set of rule based algorithms to the acquired physiological data in order to generate the reference information displayed to the clinician. Rather, the reference information displayed to the clinician is displayed as a result of the clinician's own interpretation of the diagnostic image and the clinician's selection of that interpretation. As such, the displayed reference information is not a diagnostic interpretation, but rather is merely the display of additional reference materials to aid in the clinician's interpretation of the diagnostic image.

Therefore, for the reasons stated above, Rottem fails to teach the method claimed in claim 11 where a first rule set is applied to acquired physiological data in order to generate a first diagnostic interpretation and a second rule set is applied to acquired physiological data to generate a second diagnostic interpretation and claim 11 is thus believed allowable over the cited Rottem reference.

Claim 12

The Examiner has rejected claim 12 as being fully anticipated by the Rottem reference. Claim 12 depends directly from independent claim 11 which, for the reasons stated above, is believed to be allowable. As such, claim 12 is believed to be allowable based on these reasons, as well as the subject matter recited therein.

Presently amended claim 12 further recites the step of determining the first set of rule-based algorithms to apply to the acquired physiological data stream comprising displaying a list of choices to a clinician and receiving a clinician input indicative of a selection made by the clinician. Rottem fails to teach these additional requirements of presently amended claim

12. There are two points in the disclosure of Rottem in which the clinician may make a selection. Neither of the selections by the clinician described by Rottem result in a selection of a first set of rule-based algorithms.

The first instance where the clinician may optionally make a selection is when the clinician may identify the diagnostic image, or the organ systems within the diagnostic image, that is to be analyzed by the system. After the clinician makes this selection, the "core matrix" is displayed that lists the relevant organ system and the conditions that may affect those organ systems. The "core matrix" is not generated by an application of a first rule set to the physiological data, but rather is simply an index of the identified organ system and the conditions that may affect those organ systems.

The second time that the clinician is allowed to perform a selection is when, based on the clinician's own interpretation of the diagnostic image, the clinician selects and intersection between an organ system and a condition in the "core matrix". Upon this selection by the clinician, the system of Rottem displays additional reference information regarding the selected organ system and selected condition to the clinician. Once again, this display of information is not based upon the application of a first rule set to the acquired physiological data, but rather is based upon the clinician's own selection of an organ system and a condition.

Therefore, Rottem fails to teach the invention as claimed in presently amended claim 12 and claim 12 is thus believed to be independently allowable over the cited Rottem reference.

Claims 13, 14, and 69

Claims 13, 14, and 69 all depend directly and/or indirectly from independent claim 11, which is herein believed allowable. Therefore, claim 13, 14, and 69 are all believed allowable for the reasons stated above as well as the subject matter recited therein.

Claim 72

Presently amended claim 72 now includes a requirement of "applying a first rule set comprising a plurality of rule-based algorithms to the acquired at least one real-time physiological data stream, the first rule set comprising rule-based algorithms directed to

producing at least one general diagnostic interpretation of the at least one real-time physiological data stream based on the application of the first rule set; and applying the selected rule set to the at least one real-time physiological data stream; and generating at least one specific diagnostic interpretation of the at least one real-time physiological data stream based on the application of the second rule set."

Presently amended claim 72 is distinguished from the method disclosed in Rottem in that claim 72 requires at least one general diagnostic interpretation from applying a first rule set and at least one specific diagnostic interpretation from applying a second rule set. Rottem fails to teach a general diagnostic interpretation followed by a specific diagnostic interpretation, both of which are generated from the application of a rule set of rule-based algorithms to acquired physiological data. As discussed above, the information presented by Rottem is not based on the application of rule-based algorithm to physiological data, but rather Rottem merely presents the same library of information in response to the same selections made by a clinician. Therefore, the disclosure of Rottem fails to anticipate presently amended claim 72 and claim 72 is believed allowable.

Claim 74

Presently amended claim 74 has been amended to now recite the steps of "storing a plurality of rules set in a geographically diffuse manner each of the plurality of geographically diffuse rule sets being configured to produce an independent diagnostic interpretation when applied to physiological data; and selecting a first rule set from the plurality of geographically diffuse rule sets to be applied to the real-time physiological data streams."

Claim 74 as been amended to now recite the concept of storing the plurality of rule sets in a geographically diffuse manner. The rule sets used in the method of claim 74 draws upon a plurality of rule sets that are remotely located to the patient being monitored. Rottem fails to teach the storing and retrieval of rule sets spread out geographically.

Rottem fails to anticipate claim 74 and claim 74 is also believed allowable.

Claim 76

Presently amended claim 76 now recites "at least one remote database, the at least one remote database comprising a plurality of rule sets, each comprising a plurality of rule-based algorithms; a network connection connected to the controller and the at least one remote database such that the plurality of rule sets are transferred from the at least one remote database to the controller."

Rottem fails to teach a remote database storing a plurality of rule set and a network connection connected between the controller and the remote database such that the plurality of rule sets are transferred from the remote database to the controller. Rottem is silent in its teaching towards the remote store of rule set and the acquisition of those remotely stored rule set by a controller for processing physiological data.

Therefore, claim 76 is not anticipated by the disclosure of Rottem and as such is believed allowable.

Claim Rejection Under 35 USC §102(e)

Claims 78 and 81 both additional recite that the physiological data stream is that of a biopotential signal. As addressed, neither the Rottem nor the Iliff references include disclosure pertaining specifically to biopotential signal. Thus the inclusion of biopotential signals in these claims further distinguish the invention from that disclosed in the cited references.

Claims 1-3, 5-11, 13, 14, 16, 17, 28, 69, and 71-76 all stand presently rejected by the Examiner under 35 U.S.C. §102(e) as being anticipated by Iliff. Claim 20, 22, 24, 25, 27, 61, 66, 67, and 70 also stand rejected but have been cancelled, thus rendering those rejections moot.

Iliff discloses a panel diagnostic method and system for computerized medical diagnostics. The system obtains one or more patient health items, such as an indication that the patient is experiencing pain, feeling weak, has a cough, fever, or is vomiting, or has lost weight. These patient health items are evaluated using multiple strategy differential diagnosis with different analysis criteria of the patient health item. The

system then recommends an action or provides a diagnosis to the patient or a healthcare professional based upon this analysis.

Iliff, however, fails to teach a plurality of sensors generating a real-time physiologic data stream, said real-time physiologic data stream including a plurality of physiologic variables, as required by claim 1. Claim 1 requires a system for assisting a physician in properly diagnosing the physical condition of a patient. The purpose of the system is to give the clinician the ability to correlate the plurality of physiological variables that are being currently monitored from the patient, in order to identify a diagnostic interpretation that may not be readily apparent to a clinician if the clinician must interpret each of these physiological variables on their own. The presently claimed system does this by requiring a plurality of sensors which generate a real-time physiologic data stream. This real-time physiologic data stream generated from the plurality of sensors is not disclosed by Iliff. Instead, as Iliff discloses the collection of patient health items entered by the patient or the patient's proxy, through tools such as a questionnaire. These tools and the resulting patient health items, while relevant to diagnosing the physical condition of the patient, are completely different from the claimed real-time physiologic data stream including a plurality of physiologic variables both in terms of the information conveyed, as well as the complexity of the interpretation needs of the collected data.

Furthermore, the entry of patient health items by a patient or the patient's proxy does not anticipate the use of a plurality of sensors to generate a real-time physiologic data stream. The real-time physiologic data stream comprises the rote collection of bio-potentials or other physiological data, whereas the entry of patient health items is subject to the patient's, or the patient's proxies own analysis of the patient's physiological condition. This additional piece of the system disclosed by Iliff introduces increased subjectivity and therefore error into the automated diagnostic system.

Therefore, for the reasons stated above, Iliff fails to anticipate the invention as claimed in claim 1.

Claims 2, 3, 5-9 and 68 all depend directly and/or indirectly from independent claim 1, which is herein believed allowable. Therefore, claims 2, 3, 5-9 and 68 are also believed allowable for the reasons stated above as well as the subject matter recited therein.

Claim 10

Claim 10 depends directly from independent claim 1 which is herein believed allowable. Claim 10 adds the additional requirement of a plurality of network medical facilities in communication with said controller such that said first logic rule set may be received from any of said plurality of network medical facilities. The Iliff reference, as well as the patents incorporated by reference therein, fail to teach this additional requirement of a plurality of network medical facilities, from which the first logic rule set may be received. As Iliff fails to teach the storage and retrieval of the first logic rule set from a network medical facility, Iliff fails to anticipate claim 10 and claim 10 is therefore believed to be independently allowable.

Claim 11

Presently amended claim 11 recites a method for providing diagnostic aid to a clinician monitoring the medical condition of a patient and includes the steps of acquiring a physiological data stream from at least one sensor connected to the patient and applying at least one rule-based algorithm from a first set of the rule-based algorithms to the acquired physiological data stream.

Iliff does not anticipate presently amended claim 11 as Iliff fails to teach a step of acquiring a physiological data stream from at least one sensor connected to a patient. The system disclosed by Iliff requires the entry of patient health items by the patient or the patient's proxy. This is not a physiological data stream obtained from at least one sensor connected to the patient, rather this represents the discrete entry of patient health items into a system that is first subject to the interpretation of the patient's health by the person answering the health item questions.

The application of a rule-based algorithm to a plurality of discreet patient health items is different, and thus does not anticipate the application of at least one rule based algorithm to the acquired physiological data stream. The analysis of a stream of physiological data requires different algorithms and produces different results from that analysis.

As such, Iliff fails to anticipate presently amended claim 11.

Claims 13, 14, 16, 17, 69, and 71

Claim 13, 14, 16, 17, 69, and 71 all depend directly and/or indirectly from independent claim 11, which is herein believed allowable. Therefore, for the reasons stated above, as well as the subject matter recited therein, claims 13, 14, 16, 17, 69, and 71 are all also believed allowable.

Claims 72, 74, and 76

Presently amended claims 72, 74, and 76 are all presently amended independent claims and are herein believed allowable. These independent claims have been amended to further specify and point out that the patient data is at least one real-time physiological data stream. As addressed above, Iliff fails to teach the acquisition and analysis of at least one real-time physiological data stream, instead focusing on the collection and analysis of discrete patient health items. Additionally, claim 74 and 76 have been amended to include the additional requirement of storing the rule sets at a remote location to the patient. The remote distribution and storage of the rule sets allows for increased collaboration between healthcare facilities and the improved localized development of new algorithms and rule sets that may be efficiently shared among a region or network of remotely located institutions.

Iliff fails to teach the storage of a plurality of rule sets at different remote locations and the resulting retrieval of the stored rule sets from these remote locations.

Therefore, presently amended independent claims 72, 74, and 76 are all distinguished from and not anticipated by the cited Iliff reference.

Claims 28 and 73

Claims 28 and 73 both depend directly from independent claim 72, which is herein believed allowable. Therefore, claims 28 and 73 are also believed allowable for the reasons stated above as well as the subject matter recited therein.

Claim 75

Claim 75 depends directly from independent claim 74, which is herein believed allowable. Therefore, claim 75 is also believed allowable for the reasons stated above as well as the subject matter recited therein.

New Claims 77-84

New claims 77-84 have been added to the present application. Claims 77-80 depend directly and/or indirectly from presently amended claim 76, which is herein believed allowable; claims 81-83 depend directly and/or indirectly from independent claim 72, which is herein believed allowable; and claim 84 depends directly and/or indirectly from claims 11 and 12, which are herein believed allowable.

Claim 77 adds the first requirements of a rule set acquisition logic and a build generator connected to the rule set acquisition logic. The rule set acquisition logic and the build generator connected to the rule set acquisition logic allow for the system claimed in claim 76 to further provide a clinician with an ability to acquire a remotely located rule set, gained access to the rule set by the agreement to pay a prescribed fee, and secure the transfer of the rule set to the controller used by the clinician. This concept and these features are not taught by either of the cited Iliff or Rottem references and therefore, is believed to be allowable over the cited art.

Claims 79, 80, 83, and 84 all recite additional requirements directed towards the selection of the second rule set based upon an analysis of the first diagnostic interpretation and a clinician's selection of a second dataset based upon that analysis. These additional steps are not taught in either the Iliff or the Rottem references and therefore, are believed to be allowable over the cited art.

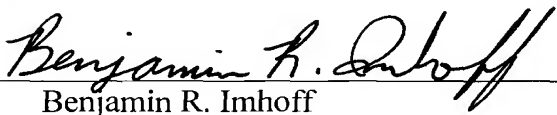
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Conclusion

The present application is believed to be in a condition for allowance over the references cited by the Examiner. Claim 1-3, 5-14, 16, 17, 28, 68, 69, and 71-84 are all believed allowable and not anticipated by either the Rottem or Iliff references. Such action is earnestly requested.

Respectfully submitted,

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